

REMARKS

Following entry of the foregoing amendment, claims 1-6 are pending in the instant application. Support for amended Claim 1 appears in at least Claims 1 and 2 as originally filed and Example 1. The foregoing amendment was made without any intention to abandon any subject matter, but with the intention that one or more claims of the same, lesser, or greater scope may be pursued in a later application or in a continuation, continuation-in-part, or divisional application. The present amendment does not add new matter. The sole basis for the Examiner's rejection of Claims 1-6 is addressed below.

Rejection of Claims 1 and 2 Under 35 U.S.C. §102(b)

The Examiner has maintained the rejection of prior record of Claims 1 and 2 under 35 U.S.C. §102(b) as being inherently anticipated by Hastings *et al.* (U.S. 5,626,849). Since the claims are now drawn to the treatment or amelioration of chronic inflammation, the Examiner appears to have abandoned their former reasoning the Record (Page 2 of the Office Action dated January 7, 2009) that the claims were inherently anticipated because they are not drawn to a specific type of inflammation, they read on any types of inflammatory process in the body. The Examiner reasserts that Hastings *et al.* teach the use of (-)-hydroxycitric acid for the purpose of weight loss, and that there "has to be some type of inflammation in the body at any given moment." (Page 2 of the Office Action dated August 13, 2009). In fact, Hastings *et al.* describes a complex formulation which includes multiple bioactive ingredients such as gamma- linoleic acid, L-carnitine, Coenzyme Q10 and (-)-hydroxycitric acid designed to burn fat stores as well as reduce fat synthesis (see Hastings *et al.* at Col. 2, lines 14-28). The Applicants respectfully traverse and assert that Claims 1 and 2 as presently amended obviate the rejection of Claims 1 and 2 under 35 U.S.C. §102(b) as being inherently anticipated by Hastings *et al.* (U.S. 5,626,849).

As noted above, Hastings *et al.* describes a complex formulation which includes multiple bioactive ingredients such as gamma-linoleic acid, L-carnitine, Coenzyme Q10 and (-)-hydroxycitric acid designed to burn fat stores as well as reduce fat synthesis (see Hastings *et al.* at Col. 2, lines 14-28). Hastings *et al.* teaches that gamma-linoleic acid is known to have anti-inflammatory property. (Hastings *et al.* at Col. 4, lines 1-20). As such, it is unclear, how one could specifically attribute a putative anti-inflammatory action of the composition taught by Hastings *et al.* to hydroxycitric acid based on the teaching of this reference.

As amended, Claim 1 is drawn to a method of treating or ameliorating chronic inflammation in a subject comprising orally administering a therapeutically effective amount of (-)-hydroxycitric acid. Claim 2 which depends from Claim 1, provides that the (-)-hydroxycitric acid is supplied in a therapeutically effective amount of the free acid or its lactone. A reference is said to inherently anticipate a claim if the cited reference necessarily and inevitably produces the claimed result upon performance of

the method steps (*Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)). The Applicants assert that the teachings of Hastings *et al.*, do not necessarily or inevitably produce treatment or amelioration of chronic inflammation.

As shown in Example 1, of the instant application, the effect of bimetal salts of hydroxy citric acid on reduction of C-reactive protein, a marker of inflammation, was observed to be concentration dependent (Specification at ¶¶ [0023] through [0024]). As such, the subject would require a therapeutically effective amount of a composition comprising hydroxy citric acid to ameliorate or treat chronic inflammation. There is nothing in the teachings of Hastings *et al.* that inherently anticipate Applicant's claimed invention as Hastings *et al.* does not teach administration to a subject suffering from treatable inflammation nor does Hastings *et al.* teach administration of an therapeutically effective amount effective for treating chronic inflammation. There is no evidence that there "has to be some inflammation in the body at any given moment" [Emphasis Added] or that a subject with inflammation is suffering from chronic inflammation or that the mere presence of a hydroxy citric acid at any concentration would ameliorate or treat a subject suffering from chronic inflammation. There is no guidance in Hastings *et al.* as to what amount of (-)-hydroxycitric acid would constitute a therapeutically effective amount to treat or ameliorate chronic inflammation even if it existed in a subject. Consequently, the Applicants' assert that Examiner's reasoning that the use of hydroxycitric acid for any purpose in the body would inherently ameliorate or treat inflammation, "considering that there has to be some type of inflammation in the body at any given moment" is erroneous. (Office Action dated August 13, 2009 at page 2) There is no evidence that the teachings of Hastings *et al.* would necessarily and inevitably produce the claimed result upon performance of the method steps (*Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003)). In light of these remarks, reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 4-6 Under 35 U.S.C. §102(e)

The Examiner has maintained the rejection of April 30, 2008 of Claims 4-6 under 35 U.S.C. §102(e) as being inherently anticipated by Clouatre *et al.* (U.S. 6,447,807). The Examiner asserts that Clouatre *et al.* teach the use of (-)-hydroxycitric acid in a sustained release form for the purpose of weight loss and appetite suppression. The Examiner reasons that the use of (-) hydroxycitric acid in a formulation as a weight loss and appetite suppressant agent would inherently treat and ameliorate "any inflammation" in the body because the inflammatory process can be caused with any types of imbalance and therefore the human body is always dealing with certain type of inflammation which can be silent and not obvious to the eye. (Page 3 of the Office Action dated August 13, 2009). As amended, Claim 1 is drawn to a method of treating or ameliorating chronic inflammation in a subject comprising orally

administering a therapeutically effective amount of (-)-hydroxycitric acid. Claims 4-6 depend from Claim 1, and therefore, incorporate all the limitations of the base claim. Accordingly, the Applicants respectfully traverse and assert that Claims 4-6 as presently amended obviate the rejection Claims 4-6 under 35 U.S.C. §102(e) as being inherently anticipated by Clouatre *et al.* (U.S. 6,447,807).

As noted above, a reference is said to inherently anticipate a claim if the cited reference necessarily and inevitably produces the claimed result upon performance of the method steps (Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379 (Fed. Cir. 2003)). The Applicants assert that the teachings of Clouatre *et al.*, do not necessarily or inevitably produce treatment or amelioration of chronic inflammation. As shown in Example 1, of the instant application, the effect of bimetal salts of hydroxy citric acid on reduction of C-reactive protein, a marker of inflammation, was observed to be concentration dependent (Specification at ¶¶ [0023] through [0024]). As such, the subject would require a therapeutically effective amount of a composition comprising hydroxy citric acid to ameliorate or treat chronic inflammation.

There is nothing in the teachings of Clouatre *et al.* that directly anticipates the claimed invention, as Clouatre *et al.* do not teach treating chronic inflammation. Also, there is nothing in the teachings of Clouatre *et al.* that inherently anticipates Applicant's claimed invention as Clouatre *et al.* do not teach administration to a subject suffering from treatable inflammation nor do they teach administration of an amount effective for treating chronic inflammation. There is no evidence that every subject suffers from chronic inflammation or guidance as to what amount of (-)-hydroxycitric acid would constitute a therapeutically effective amount to treat or ameliorate chronic inflammation. As such, the Applicants assert that the Examiner erroneously reasons that the use of (-) hydroxycitric acid in a formulation as a weight loss and appetite suppressant agent would inherently treat and ameliorate "any inflammation" in the body because the inflammatory process can be caused with any types of imbalance and therefore the human body is always dealing with certain type of inflammation which can be silent and not obvious to the eye. In light of these remarks, reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

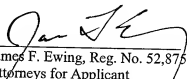
The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§1.16 1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If an extension of time is needed for timely acceptance of papers submitted herewith, Applicants hereby

petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fee to Deposit Account No. 19-0741.

Applicant respectfully submits that the pending claims are in condition for allowance and respectfully request the same. If there are any questions regarding these remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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